

Top ten tips and tricks for a successful research outline

1. Read the full application form (including guidance notes) before you begin.

All submissions must be made through our online platform (<https://kce.smartsimple.ie/>). A Word version of the form, with guidance notes, is available in the “Downloads” section of the [call](#) page. Reading these notes first will help you prepare a stronger, more complete proposal and increase your chance of success.

2. Contact a clinical trial centre and legal advisors early in the process.

To ensure all scientific, organisational and regulatory requirements are met, your proposal must be developed in collaboration with a clinical trial centre (CTC) affiliated with a non-commercial entity. Therefore, KCE strongly recommends you to contact one of these centres as soon as possible to ask if they are willing to support your research proposal.

If your study involves medicinal products or medical devices, contact your legal advisors or technology transfer office (TTO) early to make sure that your ability to conduct the study and implement its results is not legally limited and that you are able to comply with the KCE terms and conditions.

3. Make sure your research question is relevant for current Belgian practice.

KCE Trials funds practice-oriented comparative effectiveness and drug-repurposing trials. Comparative effectiveness trials compare the benefits and harms of different treatment options that are already in use in the health care system, but which have never been adequately compared directly (i.e. which of two treatments work better in a real-life situation). Accepted study interventions for such trials include a broad range of interventions for example psychotherapy, diet, life-style interventions, diagnostic tests, surgery, drugs, or medical devices.

4. Explain why more randomised research is needed.

Clearly explain the rationale for the trial, the current evidence and the situation in Belgium. Some reviewers may not be experts in your field. The need for evidence can, for example, be demonstrated by a systematic review of existing evidence that shows inconclusive results or the lack of high-quality randomised trials that directly compare several existing treatment options. Also verify that no similar randomised trials are currently ongoing or nearing publication. Make explicit what your study will add and how it will support healthcare (payer) decision-making.

5. Use a pragmatic approach in your trial design.

A pragmatic trial is designed to test interventions in the full spectrum of everyday clinical practice in order to maximise applicability and generalisability. The research question investigates whether an intervention actually works in real life. Pragmatic trials should, as far as possible, reflect the full range of patients who would receive the treatment in daily care. Furthermore, the setting and the way the studied interventions are applied should copy routine practice as closely as possible. Pragmatic trials should measure patient-centred outcomes and only data that are essential for analysis of important outcomes should be collected.

In making your trial as pragmatic as possible, please take into account existing waivers that exist for non-commercial trials and the following document that may provide practical ideas as to how pragmatic approaches can be implemented in studies: “MRC/DH/MHRA Joint Project document on Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products”. You will find this document and other interesting articles on the [Resources for investigators webpage](#).

6. Clearly define the primary endpoint.

Specify the primary endpoint precisely: what it is, how it will be measured and at what timepoint. This is essential for reviewers and is a frequent weakness in proposals. The primary endpoint must also be the basis for the sample size calculation. Use patient-centred outcomes and include the core outcome set, if one exists.

7. Describe the sample size calculation so it can be replicated.

Your sample size calculation must be transparent and reproducible for the Trials Board composed of trials methodology experts that will review your proposal. Provide all assumptions and parameters clearly. It is highly recommended to have the support of a biostatistician.

Guidance on how to calculate the sample size is available in the KCE protocol template on the [Resources for investigators webpage](#) under the “Statistics and Data Analysis” section.

8. Involve patient representatives in the design and throughout the study lifecycle

Design your trial in such a way that the question and results truly matter to patients. Involving patient representatives from the outset helps ensure that the research question, outcomes, and procedures are relevant, acceptable, and feasible. Guidance questions for patient and public involvement are available in the patient involvement plan in the “Downloads” section of the [call page](#). Additional resources can be found at <http://www.eu-patient.eu> and on [the Resources for investigators webpage](#).

9. Consider a possible health economic analysis during study design

Because improving the efficiency of the Belgian health care system is a core goal of KCE Trials, your study should anticipate the potential need for a later economic evaluation (depending on the effectiveness results). Collect variables during the trial that would be essential for such an analysis. Health economists, either at your institution or at KCE, can advise on what to include. Reflect early on how your results could influence healthcare practice, costs, and implementation.

You will find interesting articles on economic evaluation on the [Resources for investigators webpage](#).

10. Build a multicentre project team and plan implementation from the start of your study

KCE Trials stimulates collaboration across Belgian sites and institutions. Develop your research outline with a multisite team to ensure broad support, right from the beginning. KCE trials also strongly recommends appointing a co-chief investigator from the other language region to facilitate collaboration across different sites in Belgium’s three regions.